

**Notice of Allowability**

Application No.

09/993,180

Examiner

William W. Moore

Applicant(s)

CHEN ET AL.

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the Brief on Appeal filed 20 September 2005.
2. ☒ The allowed claim(s) is/are 53-59, 61-66, 76 and 77.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_;

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date ~~20040924 & 20050920~~ 10-27-04 & 2-9-05
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_\_
7. ☐ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

## DETAILED ACTION

The following is an examiner's statement of reasons for allowance:

The record establishes that a LSI-01 polypeptide having the amino acid sequence encoded by a polynucleotide of claims 53-59 and 77 shares a significant degree of amino acid sequence homology with prior art members of a class of serine protease inhibitors, serpins, and the specification specifically discloses at page 6, lines 2-3, that a this polypeptide inhibits serine proteases "exhibiting Arg/Lys specificity", i.e. those that cleave a polypeptide or peptide at a site adjacent to either of the basic amino acids arginine or lysine. The Brief on Appeal filed 20 September 2005 notes this disclosure at page 9 and at page 8 points out the requirement of MPEP § 2107 that a statement of a specific and substantial utility be considered as true, i.e., credible, unless countervailing evidence can be provided to show that one of ordinary skill in the art would have a legitimate basis to doubt the credibility of such a statement. The further arguments made in the Brief on Appeal need not be considered because the disclosure of Table III of the specification, which is an appendix to the specification that approximates the conformation of the amino acid sequence of SEQ ID NO:2 to occupancy of the three-dimensional structure of the amino acid sequence the human  $\alpha_1$ -antitrypsin inhibitor, a serpin, as well as the disclosure of Ni et al., US 6,753,164, made of record herewith, and Pan et al., made of record with Applicant's Information Disclosure Statement filed 29 October 2004, are evidence that one of ordinary skill in the art would have had a reasonable basis for concluding that a nucleic acid molecule of claims 53-59 and 64-66, 76 and 77, as well as vectors, recombinant host cells and recombinant methods of making of claims 61-63 had a specific and substantial utility at the time the specification was filed: the capacity to encode and produce a serpin that would inhibit serine proteases that cleave polypeptides or peptides adjacent to either arginine or lysine.

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Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

*Conclusion*

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William W. Moore whose telephone number is 571.272.0933 and whose FAX number is 571.273.0933. The examiner can normally be reached Monday through Friday between 9:00AM and 5:30PM EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisory Primary Examiner, Dr. Kathleen Kerr, can be reached at 571.272.0931. The official FAX number for all communications for the organization where this application or proceeding is assigned is 571.273.8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571.272.1600.

William W. Moore  
14 October 2005

  
NASHAAT T. NASHED PHD.  
PRIMARY EXAMINER